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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,940	09/27/2006	Feng Xu	PP019817.0003	4572

27476 7590 06/23/2010

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
06/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,940	XU, FENG	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,25-29,36-40 and 45-48* is/are pending in the application.

4a) Of the above claim(s) *26,28,29,37,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,25,27,36,38 and 45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-17-10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 14-24, 30-35 and 41-44 have been canceled. Claims 45-48 have been added. Claims 1-13, 25-29, 36-40 and 45-48 are pending.

Election/Restrictions

This application contains claims 26, 28, 29, 37, 39 and 40 drawn to an invention nonelected with traverse in the reply filed on 4-23-09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-13, 25, 27, 36, 38 and 45-48 are under consideration as they relate to the species Shigella.

Applicant's arguments filed 11-25-09 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-13, 25, 27, 36 and 38 remain and claims 45-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for expressing an immunogen in vivo by administering a Shigella bacterial host cell to a mammal, wherein said Shigella comprises a plasmid encoding an immunogen, wherein the Shigella is unable to use its own machinery to express the encoded immunogen, wherein the immunogen is expressed in vivo by cells of the mammal, does not reasonably provide enablement for any polynucleotide encoding an immunogen. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims encompass using any nucleic acid sequence encoding an immunogen to express the immunogen via a killed Shigella because the polynucleotide can still be with the host cell genome which includes any nucleic acid sequence including a retrovirus. The claims are not limited to plasmids or replicons and are not limited to plasmids or replicons in the host cell genome. Furthermore, a replicon encompasses any sequence capable of independent replication and is not limited to nucleic acids having a single origin of replication. The specification discusses polynucleotides on pg 4, 2nd paragraph, but the examples are limited to using plasmids. The specification does not correlate the use of plasmids to using linear strands of non-plasmid DNA, to RNA, to replicons (DNA or RNA) or to any virus (including retrovirus, specifically HIV) as the polynucleotide. It would have required those of skill undue experimentation to determine how to use any polynucleotide, specifically linear strands of non-plasmid DNA, RNA, replicons (DNA or RNA) or any virus including retrovirus (especially HIV) to express immunogens in mammals as claimed.

Applicants argue the claims as amended overcome the rejection. Applicants' argument is not persuasive because the polynucleotide can still be with the host cell genome which includes any nucleic acid sequence including a retrovirus. The claims are not limited to plasmids or replicons and are not limited to plasmids or replicons in the host cell genome. Furthermore, a replicon encompasses any sequence capable of

independent replication and is not limited to nucleic acids having a single origin of replication. Applicants have not compared plasmids to replicons (either DNA or RNA), retroviruses or any other nucleic acids to enable the breadth claimed.

Applicants' arguments regarding linear plasmids are noted; however, plasmids (linear or circular) are enabled. Non-plasmid linear DNA, i.e. oligonucleotides, et al., are not enabled.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-8, 9, 12, 13, 25, 27, 36 and 38 remain and claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003) as supported by zur Megede (J. Virol. 2000, Vol. 74, pg 2628-2635) in view of Masschalck (Applied and Environmental Microbiology, Vol. 67, No. 1, pg 339-344) and Raettig (Zentralblatt fuer Bakteriologie Mikrobiologie und Hygiene 1 Abt originale A, 1981, Vol. 205, No. 4, pg 511-520, abstract only).

Xu administered attenuated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen (pg 644-645, section 2.1; pg 645-646, section 3.1). The Shigella were attenuated because they had mutant genes (pg 644, col. 2, section 2.1). The promoter used to express the antigen was a CMV promoter as supported by zur Megede (pg 2629, col. 1, line 17), which is "a promoter functional in a eukaryotic cell." Xu did not teach the cell was "unable to use its own machinery to express the encoded immunogen" or inactivating the cells.

However, Masschalck inactivated Shigella using lysozyme under hydrostatic pressure, and Raettig heat inactivated Shigella. These techniques inherently result in Shigella to be "unable to use its own machinery to express the encoded immunogen" as claimed because the cells are inactivated.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to administer Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen as described by Xu using Shigella that had been inactivated using lysozyme treatment described by Masschalck or heat inactivation described by Raettig. Those of ordinary skill would have been motivated to inactivate Shigella using lysozyme treatment described by Masschalck or heat inactivation described by Raettig instead of merely attenuating the cells to prevent replication of the cells, prevent infection, and prevent dysentery.

Applicants argue Xu invented the claimed subject matter prior to 10-25-02. Applicants provide a declaration by Xu that states the killed E. coli and Shigella comprising a plasmid encoding an antigen could generate immune responses against the antigen in an animal prior to 10-25-02. Applicants' argument is not persuasive. The statement in paragraph 3 is not as broad as the claims or the teachings of Xu. The declaration does not teach the bacteria used prior to 10-25-02 were heat killed as in claim 2, for example. While paragraphs 4-5 describe other results, it is not clear those results were also obtained prior to 10-25-02 and correlate to specific limitations set forth in dependent claims. Applicants argue the fact that there were co-authors on the Xu

reference is irrelevant when filing a declaration under CFR 1.131. Applicants' argument is not persuasive if the co-authors contributed to the claimed invention. The declaration does not state that Xu alone demonstrated all of the claimed invention prior to 10-25-02. It is noted that the declaration does not provide notebook dates for the data.

2. Claims 1-13, 25, 27, 36 and 38 remain and claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003) as supported by zur Megede (J. Virol. 2000, Vol. 74, pg 2628-2635) in view of Masschalck (Applied and Environmental Microbiology, Vol. 67, No. 1, pg 339-344) and Raettig (Zentralblatt fuer Bakteriologie Mikrobiologie und Hygiene 1 Abt originale A, 1981, Vol. 205, No. 4, pg 511-520, abstract only) as applied to claims 1, 2, 5-8, 9, 12, 13, 23-25, 27, 34-36 and 38 and further in view of Chang (Applied and environmental microbiology, June 1985, Vol. 49, No. 6, pg 1361-1365, abstract only), Kruithof (Proceedings – Annual Conference, American Water Works assoc. 2000, pg 331-344, abstract only) and the applicant-acknowledged art at the time of filing.

The combined teachings of Xu, Masschalck and Raettig taught administering heat inactivated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice to generate an immune response against the antigen (see obviousness rejection above). The combined teachings of Xu, Masschalck and Raettig did not teach the cell was inactivated using UV light exposure or hydrogen peroxide.

However, Chang taught inactivating Shigella using UV light exposure (see abstract) and Kruithof inactivated a variety of bacteria using UV light exposure.

Furthermore, applicants acknowledge that inactivating cells was standard in the art at the time of filing including UV light exposure (pg 6, lines 17-19). These techniques inherently result in Shigella to be "unable to use its own machinery to express the encoded immunogen" as claimed because the cells are inactivated.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to administer inactivated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen as described by the combined teachings of Xu, Masschalck and Raettig using UV light treatment as described by Chang and Kruithof and acknowledged by applicants as being known in the art. It also would have been obvious to those of ordinary skill in the art at the time the invention was made to administer inactivated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen as described by the combined teachings of Xu, Masschalck and Raettig using hydrogen peroxide treatment as described by Kruithof and acknowledged by applicants as being known in the art. Those of ordinary skill would have been motivated to inactivate Shigella using UV light treatment or hydrogen peroxide instead of heat inactivation because Kruithof taught UV treatment and hydrogen peroxide the "ultimate solution for pesticide control and disinfection" (see title).

Applicants argue Xu invented the claimed subject matter prior to 10-25-02 for reasons cited above. Applicants' argument is not persuasive for reasons cited above.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner